

REMARKS

The Examiner stated that claim 87 makes reference to axial structural strands as being a part of the invention, and this claim is a dependent claim from claim 65 which does not include axial structural strands as a part of the invention. Applicants have amended claim 87 by eliminating reference to axial structural strands as a part of the claimed invention thereby making claim 87 clear.

The Examiner rejected claims 65-91 as being unpatentable over Polansky (3,304,557); the Examiner has focused on the terminology found in the independent claims 65-67. The Examiner states that strands numbered 14 from Polansky are flexible circumferential strands. The Examiner further states that some of the strands numbered 14 can be considered circumferential "structural strands" because they provide a structural component to the prosthesis. Upon examination of the Polansky specification, the Applicants were not able to find any reference to strands 14 as structural strands or reinforcing strands by Polansky; instead he refers to strands 15 and 16 as his "reinforcing strands" and they provide a similar function to the "structural strands" of Applicants' device. Polansky refers to reinforcing strands 15 and 16 as preventing kinking (C3, L20-24). To clarify the function of the structural strands the Applicants have amended the independent claims to include the requirement that the "structural strands" also must provide anti-kinking characteristics to the tubular member of Applicants' invention; this is described in Applicants' specification, for example on page 97, line 14. This anti-kink characteristic is not provided by the flexible strands such as 14 found throughout the body of the Polansky tube; Polansky describes the reinforcing strands 15 and 16 which provide the kink resistance. The Applicants therefore ask the Examiner to reconsider independent claims 65 and 66 for allowance due to the amendments made to these claims by adding the requirement that the structural strands provide anti-kink characteristics; these claims differentiate the Polansky device from

that of the Applicants because it is clear that Polansky's strands 14 cannot be considered structural strands.

Polansky teaches in his specification that the reinforcing strands 15 and 16 are floater strands that are attached intermittently due to the weaving pattern described in C3, L46 thru C4, L30; these reinforcing strands 15 and 16 are described as being found on the outer surface. The Applicants specifically state in their independent claims 65-67 that the circumferential structural strands replace any one of the circumferential flexible strands which are required to be woven consecutively with axial flexible strands; this will thereby require that the circumferential structural strands are also woven consecutively and not intermittently like the reinforcing strands found in the Polansky device. Polansky makes reference to this intermittent structure in the bottom of column 3 and the top of column 4 where he discusses the "floater yarns" 15 and 16, and also in his claim number 1. The consecutive weave as found in Applicants' device and described in the independent claims which includes Applicants' structural strands further differentiates Applicants' device from Polansky's device which has floating reinforcing strands. Since the Polansky reinforcing strands 15 and 16 are not woven in an alternating manner over and under consecutive flexible strands as stated in the Applicants' independent claims 65-67, the Applicants request that the Examiner reconsider allowance of the independent claims in their currently amended form.

Polansky teaches in his specification that the reinforcing strands 15 and 16 are found on the outer surface only of his tube and this is also shown in all of his drawings and also in his claims. Polansky states in C4, L21-30; C3, L43-53 and throughout the specification including several claims that the reinforcing strands 15 and 16 are found on the outer surface of the tube only. The Applicants' device has the circumferential structural strands interwoven consecutively over and under such that they are not located on the outer surface only such as in Polansky's device. The Applicants have made an additional amendment to the independent claims to further clarify this difference from Polansky's device. The Applicants have added the statement that the

circumferential structural strands "are exposed an equal portion to" or "make up an equal portion of" the inner and outer surface of the tubular member. This was added to further clarify that the Applicants' structural strands are interwoven consecutively within the weave of the flexible strands and are not floating on the outer surface as described by Polansky. The floating weave pattern for the reinforcing strands of the Polansky device requires that they are not interwoven consecutively and they are not exposed in an equal portion to the inner and outer surface; Polansky's reinforcing strands are on the outer surface only. This limitation that the Applicants have added to the currently amended independent claims 65 and 67, that requires that the structural strands "are exposed to" or "make up" an equal portion of the inner and outer surfaces of the tubular member, further differentiates Applicants' device from Polansky; the Applicants respectfully request that the Examiner reconsider these independent claims and provide allowance of them.

The Examiner states on page 3 of his office action mailed 11/14/2003 that it would be obvious that the Polansky device would not significantly leak blood serum or blood cellular elements since a significant leak would destroy the intended function of conveying the blood. The Applicants respectfully disagree with the Examiner's comment. The reason for this is that for many vascular graft applications such as when excluding an aneurysm it is not acceptable to allow a porous graft wall which allow for tissue penetration due to a porous structure. Polansky describes in C1, L42-46 that the prosthesis should be porous and allow for tissue penetration; it is also very common for porous grafts to allow serum to seep through and many of the grafts require preclotting prior to implant to stop this seepage. This is different from the stated requirement of the Applicants' device which does not allow for leakage of blood serum or blood cellular elements.

The Examiner states in the middle of page 3 of the office action that the formation of a bifurcated graft as described in claim number 69 would have been obvious and that it would have been obvious that one could have formed Polansky's device into a

bifurcated graft. The Applicants do not agree that forming a woven tubular structure that could have metal strands into a bifurcated structure is obvious. Most of the bifurcated vascular grafts are formed by sewing the two legs together or sewing a leg to a trunk to form a bifurcated member; it is not obvious or desirable to sew legs together to form the bifurcated embodiment of Applicants' device; you would lose the kink resistance and structural continuity obtained from the weaving process unless the tubular member is woven as a single unit. At present the Applicants are not aware of any woven bifurcated grafts that have a circumferential structural fiber interwoven along with it.

The Examiner further states that the use of metal structural strands as described in dependent claim number 75 is obvious to use in grafts since a metal strand is very strong. The Applicants respectfully do not agree with this statement because they know of no vascular grafts on the market that incorporate a metal strand into the construction of the tubular member. The Applicants are aware of many grafts which attach metal stents or other metal members to the polymeric tube to provide for anti-kink or expansion characteristics; most of these devices have encountered problems at the junction of the metal stent with the polymeric tube.

The Examiner states on the bottom of page 3 of the office action that Polansky teaches that structural strands 15 and 16 can form a helix as described by Polansky in C5, L66-69. Polansky describes that the ring section formed by reinforcing strands 15 and 16 which is located on the outer surface of the tube can take on a helical shape or other shapes rather than a ring shape as shown in his drawings. Applicants respectfully note that Applicants' structural strands are not located on the outer surface and are not intermittent as taught and shown by Polansky. The structural strands of the Applicants' invention as claimed in claim 87 are woven consecutively as stated in the independent claims. Applicants have further described these structural strands as being exposed an equal portion to the inner and outer surface of the tubular member.

The Examiner states on the top of page 4 of the office action that it would be obvious to construct the Polansky graft such that his reinforcing strands 15 and 16 extend beyond the end of the graft to be attached to an attachment means. The Applicants' respectfully disagree with the Examiner because these reinforcing fibers are only intermittently attached; they are floating fibers as described in Polansky on C3, L44 - C4, L12 and also described in his claims. If one were to apply an axial pulling force with respect to the tube axis on the floating circumferential reinforcing strands 15 and 16 of Polansky, a stress riser would be created on the single longitudinal strand that is holding the floating strands onto the outer surface of the tube causing the floating strands to peel out of their intermittent attachment to the tube. Also, if the singular longitudinal strand that is holding the floating strands 15 and 16 in an intermittent manner is strong enough to hold against the forces being imposed by pulling on the floating stands in an axial direction with respect to the axis of the tube, then the floating strands would pull along the circumference causing the tubular member to constrict down and cause the bore of the tube to become constricted in a manner that is similar to pulling on a cinch or like tightening a lasso. The Applicants' structural strands as described in claims 90 and 91 are longitudinal in direction and are held by many circumferential strands simultaneously and therefore would allow the structural strands of Applicants' device to hold securely to an attachment means as described in applicant's specification and claims. Polansky's reinforcing strands are held intermittently as described for the floater strands 15 and 16 and therefore would not be suitable candidates to hold onto an attachment means.

The Examiner states in this third Office Action that his prior statements regarding the obviousness of non-leakage of blood serum, bifurcated tubes, use of metal strands, and extending the reinforcing strands beyond the end of the tube were not traversed by the Applicants and are therefore taken to be admitted prior art. The Applicants respectfully disagree with this statement. During our phone conversations on 04 Jun 03 with the Examiner following the first office action, mailed 04/17/2003, the Applicants

stated that Applicants' independent claims described an invention that was significantly different from that of Polansky. Applicants stated that although they felt that the dependent claims were also novel, they were focusing on the independent claims and their discussions with the Examiner and subsequent Amendment, dated 11 Jun 2003, focused on amending the independent claims. Examiner's comments regarding the dependent claims (i.e., bifurcated tubes, use of metal strands, extending structural strands beyond the end) therefore was not brought forth by the Examiner on the second Office Action, mailed 06/30/2003. Applicants' phone conversation with the Examiner on 28 Aug 03, following the second Office Action also did not touch on this subject, and the Amendment dated 27 September 2003 also did not discuss this subject. It was not until this third Office Action, mailed 11/14/2003, that the Examiner again brought up these issues. The Applicants have therefore in this third Amendment brought forth their position regarding these issues. The Applicants have again focused primarily upon constructing the independent claims to more clearly identify Applicants' invention and define important aspects of the Applicants' invention that are found in the specification and are also identified in the claims but are not taught or anticipated by Polansky. The Applicants have also addressed in this third Amendment the Examiner's concerns regarding some of the dependent claims and other concerns such as blood serum leakage, bifurcated tubes, metallic strands, and extending the reinforcing strands beyond the tube end. The Applicants respectfully request that the Examiner take the comments and changes made by the Applicants into consideration and provide allowance for these claims. Any help provided by the Examiner as needed in constructing an allowable claim would be appreciated.

Respectfully submitted,



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